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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,097	03/11/2004	Fredrik Nilsson	12578/46202	6060

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,097	NILSSON, FREDRIK	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *12,15,16,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,14,17,18,21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-21 and 24-27 are currently pending.

Claims 38-39, 44, and 47 were canceled in the amendment to the claims received on February 15, 2006.

Claims 22-23, 28-37, 40-43, 45-46, and 48-49 were canceled and claims 1-2, 7, 9, 10, 14, 21, and 24-27 were amended in the amendment to the claims received on August 25, 2006. In addition, the status identifier for claim 21 is (previously presented) however, the claim is clearly (currently amended). Applicants are requested to modify the status identifier as appropriate in response to the Office action.

Claims 1-11, 13-14, 17-18, 21, and 24-27 are currently under consideration.

Withdrawn Objections and Rejections

2. The objection to the drawings regarding the Brief Description of the Drawings is withdrawn in view of the amendments to the specification received on August 25, 2006.

3. The objection to the specification is withdrawn in view of the amendments to the specification received on August 25, 2006.

4. The rejection of claims 1-11, 13-14, 17-18, and 21-27 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claims received on August 25, 2006.

Maintained Rejections

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In addition, the text of the rejections have been altered to reflect the claim amendments received on August 25, 2006.

Claim Rejections - 35 USC § 102

6. Claims 1-11, 13-14, 17-18, 21, 25, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Minden et al. WO 02/086081 A2 (filing date April 22, 2002).

For present claim 1, Minden et al. teach methods of identifying a protein via assigning (e.g. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (e.g. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1). In addition, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0003-0004], [0030], [0036], [0048]; Figures 7-9).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (e.g. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

For present claims 9-10, Minden et al. teach that the peptides or epitopes (e.g. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (e.g. 100%) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (e.g. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (e.g. unfragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031, [0040], [0053]).

Therefore, one of skill in the art would have anticipated the presently claimed invention in view of the teachings of Minden et al.

Arguments and Response

7. Applicants argument directed to the rejection under 35 USC 102(e) as being anticipated by Minden et al. WO 02/086081 A2 for claims 1-11, 13-14, 17-18, 21, 25, and 27 was considered but was not persuasive for the following reasons.

Applicant contends that Minden et al. does not teach determination of the mass and abundance of peptides, proteins, or peptide fragments.

Applicant's argument is not convincing since the teachings of Minden et al. do anticipate the method of the instant claims. It is the examiner's position that Minden et al. do teach

determining the molecular weight or mass of the binding reagents via mass spectrometry or 2D PAGE gel electrophoresis (please refer to paragraphs [0003-0004], [0030], [0036], [0048]; Figures 7-9). Therefore, the presently claimed invention is anticipated by the teachings of Minden et al.

Claim Rejections - 35 USC § 103

8. Claims 1-11, 13-14, 17-18, 21, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001).

For present claim 1, **Minden et al.** teach methods of identifying a protein via assigning (e.g. separating) binding reagents to designated locations on an array, detecting the binding patterns, and comparing the binding pattern to a reference set (e.g. characterizing; please refer to the abstract, paragraphs [0005-0012], [0028-0032], [0035-0044], [0072-0074], [0077], [00117], Figures 1-11, and Table 1). In addition, Minden et al. teach that the molecular weight or mass of the binding reagents can be determined and that spectrometry can be utilized (please refer to paragraphs [0003-0004], [0030], [0036], [0048]; Figures 7-9).

For present claim 2, Minden et al. teach that the total protein content of a cell or tissue can be utilized as the protein mixture (please refer to paragraphs [0035], [0066]).

For present claims 3-6, Minden et al. teach that the protein mixture can be fragmented with various chemical or enzymatic methods including trypsin (please refer to paragraph [0037-0039], [0066], [00105], [00107], and Table 1).

For present claims 7-8 and 11, Minden et al. teach that trypsin cleavage forms a peptide or epitope (e.g. motif) with C-terminal lysine or arginine residues (please refer to Table 1 and paragraphs [0041-0045], [0049], [0054], [0063]).

For present claims 9-10, Minden et al. teach that the peptides or epitopes (e.g. motifs) can be at least three amino acids in length and can have at least two variable amino acids (please refer to paragraphs [0029], [0032], [0040-0046], [0054], [00113-00116]).

For present claim 13, Minden et al. teach that arrays can have different binding molecules at spatially addressable locations which bind to different binding reagents (please refer to paragraphs [0005], [0008], [0012], [0028], [0040]).

For present claim 14, Minden et al. teach that the protein mixture may comprise all (e.g. 100%) of the proteins and that the epitopes cover the binding mixture (please refer to paragraph [0035], [0040]).

For present claim 17, Minden et al. teach that the array can have 2-100 different proteins (please refer to paragraphs [0047], [0073-0074]).

For present claim 18, Minden et al. teach that the binding reagents can be antibodies (please refer to paragraphs [0029], [0056-0061], [0072]).

For present claim 21, Minden et al. teach that the proteins are compared to a reference set (e.g. characterizing; please refer to paragraphs [0005], [0028-0031], [0040]).

For present claim 25, Minden et al. teach that the reference set can include prediction about binding based on the predicted digests of a protein mixture (e.g. unfragmented; please refer to paragraph [0031]).

For present claim 27, Minden et al. teach that various binding reagents can be compared to a reference set or to other binding reagents (please refer to paragraphs [0005], [0030-0031, [0040], [0053]).

However, Minden et al. does not specifically teach determining the abundance of the proteins by the use of desorption mass spectrometry or collision induced dissociation mass spectrometry.

Barry et al. teach methods of determining the binding and mass of trypsin digested proteins (including antibodies) from a cell (including phage) or tissue sample immobilized on an array (please refer to the abstract, pages 2-6, 21-30, Figures 3-6 and 8-10, Examples 2-3).

For present claim 23, Barry et al. teach determining the abundance of proteins via MALDI-TOF (e.g. mass; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 24, Barry et al. teach MALDI-TOF (matrix assisted laser desorption ionization-time of flight) mass spectrometry (e.g. combination of both desorption mass spectrometry and collision induced dissociation mass spectrometry or CID; page 35, line 7; please refer to pages 5-6, page 32, lines 25-33, page 33, lines 21-37, pages 34-35, Figures 3-6 and 8-10, Examples 2-3).

For present claim 26, Barry et al. teach determining the abundance of the protein via MALDI-TOF including proteins from any given starting material (e.g. unfragmented parent protein; please refer to page 3, lines 28-30; pages 5-6; page 32, lines 25-33; page 33, lines 21-37; pages 34-35; Figures 3-6 and 8-10, Examples 2-3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al.

One having ordinary skill in the art would have been motivated to do this because Barry et al. teach that the use of mass spectrometry and MALDI-TOF provide semi-quantitative and quantitative results for protein microarrays (please refer to page 1, lines 20-26 and 34-37; page 2, lines 1-24; page 3, lines 5-30; Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. because of the examples provided by Barry et al. showing that trypsin digested antibody arrays can be quantitated via MALDI-TOF (please refer to Examples 2-3).

Therefore, the modification of the method of identifying proteins taught by Minden et al. with the MALDI-TOF analysis taught by Barry et al. render the instant claims prima facie obvious.

Arguments and Response

9. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001) for claims 1-11, 13-14, 17-18, 21, and 24-27 was considered but was not persuasive for the following reasons.

Applicant contends that both Minden et al. and Barry et al. teach a method that requires advanced knowledge of the identity of proteins in a sample, such that specific binders for each protein (or fragment thereof) can be separated, thereby to produce homogenous classes of proteins (or fragments thereof) as bound to an array. Whereas, the presently claimed method requires the generation of a heterogeneous class of peptides or protein or peptide fragments bound to the different types of binding molecules on an array and the user of the method does not need to have advanced knowledge of the individual proteins in a sample. Furthermore, the applicant's argue that a ratio of binders to proteins for the present method is 0.02:1. Moreover, applicant suggests that hindsight reasoning was utilized.

Applicant's argument is not convincing since the combined teachings of Minden et al. and Barry et al. do render the method of the instant claims *prima facie* obvious. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. no previous knowledge of the composition of the peptides or proteins, ratio of binders to proteins must be 0.02:1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, Minden et al. teach a heterogeneous (e.g. more than one which are different form each other) protein mixtures including the proteolytically cleaved proteins (please refer to paragraphs 29-35). Furthermore, Minden et al. teach that the protein mixture can be all of the proteins in a given organism, proteome, organ, tissue, cell, organelle, or sub-cellular localization and thus all of the proteins are not known. In response to applicant's argument that the examiner's conclusion of obviousness is based upon

improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Moreover, both Minden et al. and Barry et al: discuss utilizing mass spectrometry in methods of identifying proteins and thus are analogous art which one of skill in the art would have considered.

Please note: a typographical error was corrected in the rejection wherein the statement "determining the abundance of the proteins or the use of desorption mass spectrometry or collision induced dissociation mass spectrometry" was corrected to read "determining the abundance of the proteins by the use of desorption mass spectrometry or collision induced dissociation mass spectrometry".

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS
November 7, 2006

MARK L. SHIBUYA
PRIMARY EXAMINER